

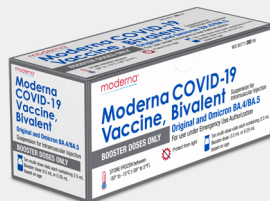
Moderna COVID-19 Vaccine, Bivalent

For individuals 6 years of age and older

AUTHORIZED USE

- Emergency uses of the vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19). The Moderna COVID-19 Vaccine is authorized in individuals 6 months of age and older as a primary series. The Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 6 years of age and older.
- The EUA for these products is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.
- For more information on the EUA authorized uses of the vaccine, refer to the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information.

Bivalent Booster Dose Presentation

Age Group	6 years of age and older
Dose Volume	Bivalent Booster Doses 12 years of age and older: Each 0.5 mL 6 through 11 years of age: Each 0.25 mL
Dose Per Vial	12 years of age and older: 5 doses 6 through 11 years of age: 10 doses
Vial Cap Color	Dark Blue 
Vial Label	Gray Border NDC 80777-282-05 
Carton	Gray Border NDC 80777-282-99 

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the vaccines to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent.

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccines. Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

See additional Important Safety Information on the following pages.

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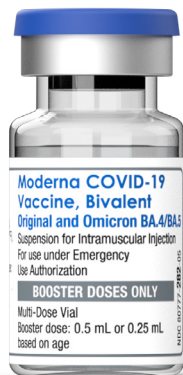
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Administration

Provide a vaccination card to the recipient or their caregiver with the date when the recipient receives a dose of the Moderna COVID-19 Vaccine, Bivalent.

The Moderna COVID-19 Vaccine, Bivalent does not require dilution. Swirl vial gently after thawing and between each withdrawal. **Do not shake or dilute.** After thawing, do not refreeze.



Prior to injection, inspect each dose to:

- Confirm liquid is **white to off-white** in color in both vial and syringe
- The vaccine may contain white or translucent product-related particulates. Do not administer the vaccine if it is discolored or contains other particulate matter
- For individuals 12 years of age and older, verify syringe volume of **0.5 mL (50 mcg)** from the vial with a dark blue cap and a label with a gray border
- For individuals 6 through 11 years of age, verify syringe volume of **0.25 mL (25 mcg)** from the vial with a dark blue cap and a label with a gray border
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials. **Record date and time of the first use on the vial label**
- Administer the Moderna COVID-19 Vaccine, Bivalent **intramuscularly**
- For more information refer to the Fact Sheet for Healthcare Providers

Bivalent Booster Dosing Schedule

Age group	Volume administered per dose	Number of Booster Doses recommended	Interval between Primary Series & Booster Doses
Eligible individuals 12 years of age and older	 0.5 mL	1	First dose 2 months
Eligible individuals 6 through 11 years of age	 0.25 mL	1	First dose 2 months

Please see "Dear HCP Letter" and Fact Sheet for more information on the Moderna COVID-19 Vaccine, Bivalent available at <https://eua.modernatx.com/covid19vaccine-eua/providers>

For any questions, contact Moderna Medical Information at:
1-866-MODERNA (1-866-663-3762)

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following receipt of the second primary series dose or first booster dose. The observed risk is highest in males 18 through 24 years of age. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

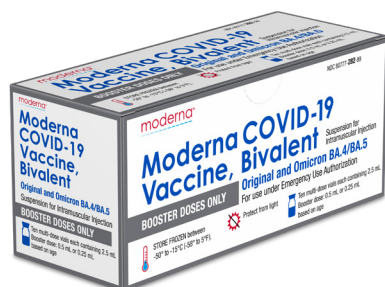
See additional Important Safety Information on the following pages.

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Moderna COVID-19 Vaccine, Bivalent

For individuals 6 years of age and older

Frozen Storage



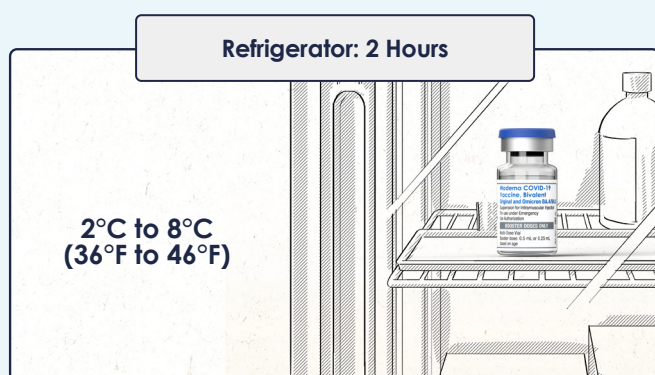
Can be stored frozen until expiration date*

-50°C to -15°C (-58°F to 5°F)

During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

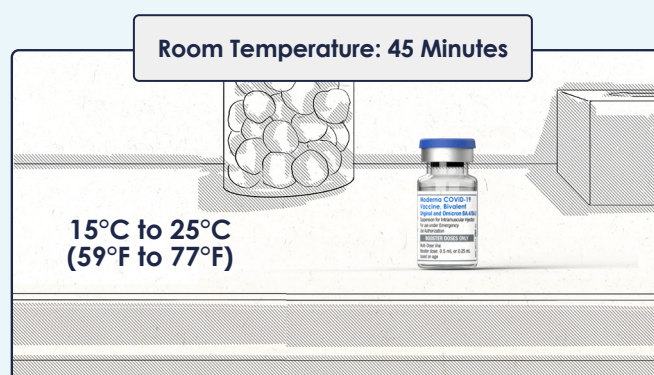
*Confirm vaccine expiration date by looking up the lot number at eua.modernatx.com/covid19vaccine-eua.

Thaw Each Vial Before Use



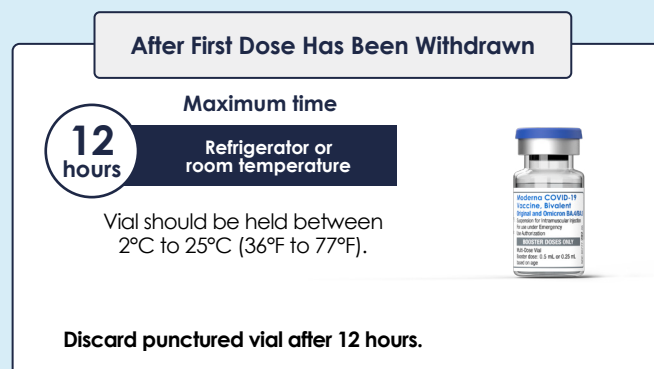
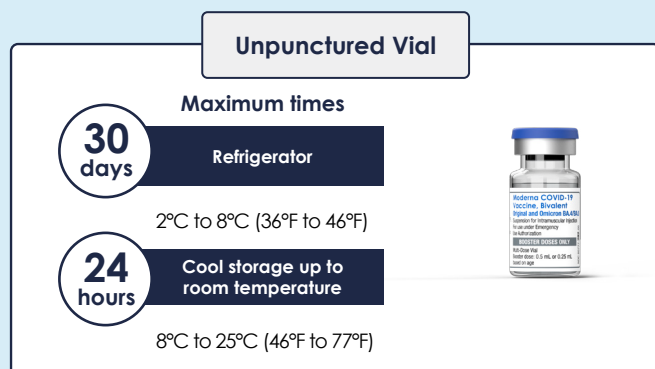
Let vial sit at room temperature for 15 minutes before administering

OR



Vial images for illustrative purposes only

Thawed Shelf Life



NEVER refreeze thawed vaccine

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

See additional Important Safety Information on the following pages.

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Moderna COVID-19 Vaccine, Bivalent

For individuals 6 years of age and older

Reimbursement Codes

Age Group	Vaccine CPT Code*	Vaccine Administration CPT Codes†	NDCs by Presentation‡	CVX Code
12 years of age and older	91313 Bivalent, 50 mcg/0.5 mL	0134A (Booster) (50 mcg/0.5 mL IM)	Primary Dose Presentation With 5 Doses Vial: 80777-282-05	229
6 through 11 years of age	91314 Bivalent, 25 mcg/0.25 mL	0144A (Booster) (25 mcg/0.25 mL IM)	Primary Dose Presentations With 5 Doses Vial: 80777-282-05	229

*If required by the payer for Centers for Disease Control and Prevention (CDC) COVID-19 vaccine acquired product, use the vaccine CPT code that describes the dose administered (1st, 2nd, 3rd, or bivalent booster) and vial presentation used. For primary series doses for individuals 6 through 11 years of age, use the Moderna COVID-19 Vaccine vial presentation labeled BOOSTER DOSES ONLY," per the Dear Health Care Provider (HCP) letter.

†The administration CPT codes align with the associated dose (1st, 2nd, 3rd, or bivalent booster) and vial presentation used for administration. CPT administration codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the records.

‡Note: For NCPDP billing, the quantity dispensed should be submitted with the value that represents the quantity of vaccine product administered (0.50 mL, 0.25 mL as appropriate).

This vaccine is available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program). To participate in the Vaccination Program, healthcare providers must enroll as providers and comply with the provider requirements. Vaccination providers in the Vaccination Program may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html>.

For questions related to billing, contact Moderna Customer Care at:
1-866-MODERNA (1-866-663-3762)

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the vaccines.
- **Limitations of Vaccine Effectiveness:** The vaccines may not protect all vaccine recipients.

See additional Important Safety Information on the next page.

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IMPORTANT SAFETY INFORMATION

Adverse Reactions

Adverse reactions reported in clinical trials for individuals 6 years of age and older following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia.

Adverse reactions in children 6 months through 5 years of age following administration of Moderna COVID-19 Vaccine include pain at the injection site, irritability/crying, fatigue, sleepiness, loss of appetite, headache, fever, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site.

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the vaccines.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of myocarditis
- cases of pericarditis
- cases of Multisystem Inflammatory Syndrome (MIS)
- cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. Reports should include the words "Moderna COVID-19 Vaccine EUA" or "Moderna COVID-19 Vaccine, Bivalent EUA" in the description section of the report.

Report to ModernaTX, Inc. by calling 1-866-MODERNA (1-866-663-3762) or provide a copy of the VAERS form by faxing 1-866-599-1342 or emailing ModernaPV@modernatx.com.

Please see the Vaccine Fact Sheets for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information for:

- **Bivalent Booster Dose for 6+ years:** <https://eva.modernatx.com/covid19vaccine-eua/bivalent-dose-HCP.pdf>
- **Primary series for 12+ years:** <https://eva.modernatx.com/covid19vaccine-eua/eva-fact-sheet-providers.pdf>
- **Primary series for 6-11 years:** <https://eva.modernatx.com/covid19vaccine-eua/6-11y-facts-HCP.pdf>
- **Primary series for 6 months-5 years:** <https://eva.modernatx.com/covid19vaccine-eua/6m-5y-facts-HCP.pdf>